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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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[REDACTED] EXAMINER

LY, CHEYNE D

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1631

9

DATE MAILED: 09/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/816,755	VAIDEHI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Cheyne D Ly	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 25 June 2003.

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-34 is/are pending in the application.

4a) Of the above claim(s) 2 and 4-34 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1 and 3 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) 1-34 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3 and 5</u> .	6) <input type="checkbox"/> Other: _____

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### **DETAILED ACTION**

1. Applicant's election without traversal of Group I, claims 1 and 3, in Paper No. 8, filed June 25, 2003, is acknowledged.
2. Claims 1 and 3 are examined on the merits.

### **OBJECTIONS**

3. The title of the invention is not descriptive due to the claimed invention is directed to a method while the instant title is directed to a method and an apparatus. A new title is required that is clearly indicative of the invention to which the claims are directed.
4. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (Page 21, Line 6). Applicant(s) is/are required to delete the embedded hyperlink and/or other form of browser-executable code, or deactivate the hyperlink. See MPEP § 608.01.

### **LACK OF ENABLEMENT UNDER 35 U.S.C. § 112, FIRST PARAGRAPH**

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1 and 3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a computer implemented method for predicting the structure of a membrane-bound proteins, bacteriorhodopsin (BRDP); and six olfactory receptors according to sequences for ORS25, ORS 18, ORS 19, ORS6, ORS46, and ORS50, does not reasonably provide enablement for computer implemented method for predicting the structure of a any membrane-bound protein. The specification does not enable any person skilled in the art

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to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

7. Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

8. It is acknowledged that Applicant has disclosed information to enable one skilled in the art to practice the computer implemented method for predicting the structure of a membrane-bound proteins, bacteriorhodopsin (BRDP); and six olfactory receptors according to sequences for ORS25, ORS 18, ORS 19, ORS6, ORS46, and ORS50 (page 19-23). Applicant discloses the structures predicted by the said method are confirmed by comparing said structures with known crystal structures. It is noted a method that relies on data from an unpredictable art such as protein crystallization would require clear and precise guidance for one skilled in the art to reliably use the said method. Applicants discloses in the instant specification that x-ray crystallography or other methods for determining protein tertiary structures are not amenable for

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determining the structures of all proteins which supports the assertion that data generated from these methods are unpredictable at best.

9. It is well documented that protein crystallization is in essence a trial-and-error method, and the results are usually unpredictable (Drenth, J.). Further, as recently as November 1, 2002, Science published a New Focus article depicting the current state of the art for protein crystallization that supports the unpredictability of the art. In essence, protein crystallization is still a trial and error process because the current technology for producing protein for the crystallization process is unpredictable, which results in high failure rate for proteins that are being crystallized. Therefore, researchers continue to have trouble generating sufficient protein required for the crystallization process (New Focus, Science, 2002). Accordingly, it would be unpredictable for one skilled in the art to practice the method for predicting the structure of membrane-bound proteins with any other protein beyond the ones described in the instant specification. In light of the difficulty of the protein crystallization process, it is, therefore, unreasonable to expect one skilled in the art to use the information disclosed for one specific set of proteins (bacteriorhodopsin (BRDP); and six olfactory receptors according to sequences for ORS25, ORS 18, ORS 19, ORS6, ORS46, and ORS50) to determine protein structures of other with predictable quality without undue experimentation.

### **CLAIM REJECTIONS - 35 USC § 103**

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rose et al. (US 5680319 A) taken with Kyte et al. (1982).

12. Rose et al. discloses a computer-implemented method for protein fold prediction based on the amino acid sequence (Abstract etc.). The method of Rose et al. comprises bundling structure in to four categories helix, ..., and loops (column 2, lines 42-46). The initial structure is determined based on a 4-helix bundle (column 8, lines 1-3). According to the initial predicted structure, helix 4 does not associate with the other three helices, a second structure is optimized according helices 1-3 (column 8, lines 35-46 and Figures 7a-7c). A final predicted structure is outputted as a result of the above mention prediction process (column 9, lines 65-67), as in instant claim 1.

13. The bundle of helices is based on the canonical helices (one of four conformations) (untitled conformation table, columns 5-6). Upon completion, the minimum energy structure is among the ensemble of conformations from the final interval (column 5, lines 4-6), as in instant claim 3.

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14. However, Rose et al. does not disclose the limitation of predicting the structure of membrane-bound protein.

15. Kyte et al. discloses a computer-implemented method for predicting the structure of membrane-bound proteins, the portions of their sequences that are located within the lipid bilayer (page 105, Abstract etc.), as in instant claims 1 and 3.

16. It is noted that Kyte et al. discloses "a useful tool (method) for the evaluation of protein structures" (Abstract etc.) and if the protein sequence has  $\alpha$ -helices etc., any sequence can be systematically scanned and the probability of those secondary structures can be evaluated (page 106, lines 21-24). Therefore, Kyte et al. suggests the said method is applicable to the any protein sequence having helices which is directed to the protein with helices disclosed by Rose et al.

17. An artisan of ordinary skill in the art at the time of the instant invention would have been motivated to partake the concept emphasized by Kyte et al. for determining the structure of membrane-bound proteins (Abstract etc.) any protein with helices to determine the protein structure disclosed by Rose et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use the computer-implemented of Rose et al. and Kyte et al. for predicting the structure of membrane-bound proteins.

### **CONCLUSION**

18. NO CLAIM IS ALLOWED.

19. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157

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OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

22. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly  
8/27/03

*Ardin H. Marschel*  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER